

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

PC5150JST

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/000743

International filing date (day/month/year)

21.01.2005

Priority date (day/month/year)

23.01.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

JAPAN SCIENCE AND TECHNOLOGY AGENCY

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000743

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/000743

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>2, 7</u>	YES
	Claims	<u>1, 3-6, 8</u>	NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-8</u>	NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: WO, 02/080936, A1 (ORTHO MCNEIL PHARMACEUTICAL, INC.), 17 October, 2002 (17.10.02)</p> <p>Document 2: JP, 11-511472, A (Ligand Pharmaceuticals Inc.), 05 October, 1999 (05.10.99)</p> <p>Document 3: Nanzando Igaku Daijiten Gokaban, 18th edition, pages 1486 to 1487, 16 January, 1998 (16.01.98)</p> <p><Claims 1, 3-6 and 8></p> <p>The subject matters of claims 1, 3-6 and 8 do not appear to be novel or to involve an inventive step in view of documents 1 and 2 cited in the ISR.</p> <p>Document 1 describes that 9-cis-retinoic acid is an antidiabetic drug (pages 26 to 27).</p> <p>Document 2 describes a method for treating non-insulin dependent diabetes mellitus (NIDDM) in which RXR agonist (9-cis-retinoic acid) is administered, and it can be prepared in the form of suspensions or particles.</p> <p>As described in document 3, a relation ship between diabetes and spleen β cells is widely known, and objects to be treated in the physiological process involving the activation of spleen β cells include diabetes in view of the descriptions of the specification of this application.</p> <p><Claims 2 and 7></p> <p>The subject matters of claims 2 and 7 do not appear to involve an inventive step in view of documents 1 and 2 cited in the ISR.</p> <p>A person skilled in the art could easily find an antidiabetic activity similarly in a stereoisomer of retinoic acid.</p> <p>A person skilled in the art could accordingly conceive that the particle diameter is experimentally set in an optimum range when providing a medical preparation in the form of particles in the inventions described in documents 1 and 2.</p> <p>The specification of this application only mentions the superiority/inferiority in the diabetes treating effect based on the presence/absence of retinoic acid, and since the diabetes treating effect of retinoic acid is publicly known, the effect of the subject matters of claims 1-8 is not found to be a noticeably remarkable effect that cannot be easily predicted by a person skilled in the art as compared to the prior art.</p>			